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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/254,966	03/16/99	CORREA R	MD-5092/LEA

HM12/1009

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EXAMINER	
WINKLER,U	
ART UNIT	**PAPER NUMBER**
1648	16

DATE MAILED: 10/09/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/254,966	Applicant(s) CORREA ET AL.	
	Examiner Ulrike Winkler, Ph.D.	Art Unit 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 August 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8 and 13-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8 and 13-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *14* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

This Office Action is the response to applicant's amendment filed 10 August 2001. Claims 1-8 and 13-27 are pending and rejected.

The text of those sections of Title 35 U.S.C. not included in this action can be found in a prior office action.

An initialed and dated copy of Applicant's IDS form 1449, Paper No. 14, is attached to the instant Office action.

In the previous office action claim 23 was erroneously included in the rejection of claims 24-27, which was readily apparent as noted by the applicant. The body of the rejection was directed to the composition and methods of differentiating between vaccinated and immunized animals set out in claims 24-27. The examiner apologizes for any confusion this may have caused, it is also apparent that such error would not unduly prejudice applicant. The rejection of claims 24-27, as they read on differentiating between infected and vaccinated animals, under 35 U.S.C. 103(a) as being unpatentable over Rodriguez et al. (Arch. Virol. 1994) and Lubroth et al. (Vaccine 1996) **is maintained** for reasons of record. The combined references teach using peptides to non-structural proteins as a means of differentiating between infected/convalescent animals and vaccinated animals.

The rejection of claims 1-8, 13-23 and 24-27 as the claims read on a composition or a process of immunizing animals against FMDV using peptides under 35 U.S.C. 112, first

paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention **is maintained**. Applicant's arguments have been fully considered but are not found convincing essentially for the reasons of record. Applicant submits that the specification enables the full scope of the claimed invention. According to the applicant ELISA based assays can provide some evidence (antibody stimulation) that peptides would be efficacious. This is not convincing, because in the previous interview with applicant, 6 September 2000, applicant argued that an antibody response in an animal to a natural infection would not be indicative of a protective prophylactic effect in an animal. Examiner agreed with applicant's arguments at the time and accordingly withdrew the art rejections, which raised the instant enablement rejection. In contrast to applicant's arguments, the evidence provided in the previously cited reference of Van Lierop et al. (Immunology 1995) clearly shows that three FMDV peptides tested were not recognized by the DH24A haplotypes. The influence of MHC polymorphism may be less apparent in response to whole viral proteins. The effect of MHC polymorphism should not be under-estimated when testing new subunit vaccines in randomly chosen groups of animals. In order to establish the efficacy of the vaccine in different MHC backgrounds the animals should be typed in advance. In order to design a peptide vaccine, which is effective in all animals, the response to different T-cell epitopes should be tested for all possible MHC haplotypes (see page 84, especially last paragraph). According to the Van Lierop et al. reference peptide vaccines in general and specifically FMDV, contemplated in the instant invention, are not predicable and must be experimentally determined. Therefore, the rejection is maintained for reasons of record.

The rejection of claims1-8, 13-23 and 24-27 as the claims read on a composition or a process of immunizing animals against FMDV using peptides under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention **is maintained**. Applicant's arguments have been fully considered but are not found convincing essentially for the reasons of record. The specification has shown linear peptides that react with antibodies in the serum from vaccinated and infected animals. Based on the objective evidence that there is a need to test each peptide for efficacy as a vaccines formulation as indicated in the reference of Van Lierop et al. (Immunology 1995) it is clear that the instant specification does not provide the requisite written description for a FMDV peptide based vaccine. Therefore, the rejection maintained for the reason cited here and in the previous action.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ulrike Winkler, Ph.D. whose telephone number is 703-308-8294. The examiner can normally be reached M-F, 8:30 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached at 703-308-4027.

The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 or for informal communications use 703-308-4426.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Ulrike Winkler, Ph.D.

JAMES HOUSEL 10/9/01
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600